

Serial No.: 09/915,773
Attorney Docket No.: 2S20.1-010

REMARKS

The Office Action mailed September 19, 2005 has been received and reviewed. Claims 1-7, 9-14, and 20-24 are pending in the application, with Claims 15-19 previously withdrawn from consideration and Claim 8 previously cancelled. No new matter is introduced.

Claims 1, 2, 4-7, 9, 11-14 and 20-24 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over U.S. Patent No. 4,468,820 to Uhler et al in view of U.S. Patent No. 5,476,513 to Brady et al. Claims 3 and 10 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over U.S. Patent No. 4,468,820 to Uhler et al in view of U.S. Patent No. 5,476,513 to Brady et al, and further in view of U.S. Patent No. 4,725,276 to Bissonette et al. Applicants respectfully traverse these grounds of rejection and request reconsideration.

For a rejection to be proper under 35 U.S.C. §103(a), there must be: (1) a suggestion or motivation to combine the references in the manner proposed, found in the references themselves or in the knowledge generally available in the prior art; (2) a reasonable expectation of success in combining the references to yield the claimed invention; and (3) the combination must teach every element in the claim. In re Vaeck, 20 U.S.P.Q. 2d 1438 (Fed. Cir. 1991); M.P.E.P. § 2143. The present grounds of rejection cannot properly be maintained, because these requirements are not satisfied.

First, there is no suggestion or motivation in the references or any other art of record for the proposed combination of Uhler et al and Brady et al. The Examiner acknowledges that the Uhler et al reference "lacks the express written disclosure of the lens being foldable". Indeed, Uhler et al discloses only a lens with a body made of unmodified polymethylmethacrylate (PMMA) or like plastic (column 4, line 41). Those of ordinary skill in the art would readily recognize that unmodified PMMA is a substantially rigid material, and that lenses made of this material would not be at all "flexible" or "rollable". Indeed, the Brady et al reference confirms this at column 1, lines 55-56, identifying PMMA lenses as "hard or rigid". Accordingly, there is no conceivable teaching or suggestion in Uhler et al

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that the lens body taught by that reference could be modified to be foldable or bendable, as proposed. And the Brady et al reference expressly distinguishes flexible lenses from "hard or rigid" PMMA lenses, effectively teaching away from the Examiner's proposed combination.

The proposed combination is also improper because the Examiner has not established any motivation or suggestion as to why one of ordinary skill in the art, seeking a solution to the problem of reducing the insertion profile of an IOL, would start with a rigid optic structure as taught by Uhler et al. Uhler et al does not even identify the problem to be solved by Applicant's invention, let alone the Applicant's presently claimed solution, because Uhler et al deals only with rigid lenses. The person of ordinary skill would never look to solve the problem of an unduly large insertion profile by turning to Uhler et al, because the lens of Uhler et al has, in effect, the largest of all insertion profiles possible--namely that of the full diameter of the optic, because the optic is rigid. Brady et al also does not disclose or suggest the above-emphasized features of Applicant's presently claimed invention, since the relatively thick peripheral edge extending entirely around the optic of the Brady et al lens is completely contrary to Applicant's solution to the problem of reducing an IOL's insertion profile.

Clearly, the only conceivable motivation for the Examiner's proposed combination is hindsight reconstruction based on Applicants' teaching, rather than a suggestion in the references, which is of course legally impermissible. In re Fine, 5. U.S.P.Q. 2d 1596, 1600 (Fed. Cir. 1988). Because there is no suggestion or motivation in the references or any other art of record for the proposed combination of Uhler et al and Brady et al., both grounds of rejection under §103 are improper and should be withdrawn.

But even if the proposed combination of references were not improper, the combined teachings of the references still would not teach every element of Applicant's presently claimed invention or yield a reasonable expectation of success. The present invention is directed generally to the provision of a flexible or rollable intraocular lens ("IOL") having a reduced insertion profile. As defined in Claim 1, the IOL includes two

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flared portions along its peripheral edge, and a "lens body being rollable *along an axis extending between said first flared portion and a second flared portion . . .*" Claim 9 similarly recites "said lens body is rollable or foldable *along an axis extending between said first and second flared portions*". And Claim 20 defines an IOL implantation method including "folding the flexible lens body *along an axis extending between the two flared portions*". The IOL of Claim 24 includes a "lens body being rollable or foldable *along an axis extending between said two flared portions*".

None of the references applied in the Examiner's proposed combinations disclose or suggest these elements of Applicant's presently claimed invention. The Examiner's statement in the Office Action of September 19, 2005, that "Brady et al teach at column 8, lines 24-34 that the lens may be folded about any axis", is an overly broad reading of the reference's actual disclosure. The Examiner misconstrues Brady et al's language at col. 8, line 32, et seq., that "[t]he fold can be along any desired diameter so as to place the fixation member in the desired position for insertion" (emphasis added).

The referenced passage would not teach or suggest to one skilled in the art that the lens of Brady et al be folded along an axis extending between its "attachment regions 29", because folding the lens in that manner would be contrary to the express requirement that the fixation members be "in the desired position for insertion". Brady et al's "desired position for insertion" is identified as "essentially the same as known procedures" (see col. 9, lines 18-20), and is illustrated in Fig. 7 of the reference. In accordance with known procedures, the lens is folded about line 3-3 (reference no. 47 in Fig. 1) of Brady et al, so that there is in effect a leading haptic or fixation member (which is the one located inside the capsular bag in Fig. 7 of Brady et al), and a lagging haptic or fixation member (located in the anterior chamber in Fig. 7). Thus the surgeon first positions the leading haptic and optic in the capsular bag and then brings in the lagging haptic. In this manner, both haptics are generally well located as the IOL is introduced into the capsular bag, since they extend in opposition directions, one diametrically opposed to the other.

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The Examiner is, in effect, suggesting that the flexible optic be folded along an axis extending 90° to the actual desired fold line of Brady et al. If the Brady et al lens were folded in this manner, both haptics would be folded to the same side of the fold line, and the free ends of the haptics would be directed at each other. Such an arrangement is clearly not suggested by Brady et al to one of skill in the art, and could be contrary to good surgical practice because in effect both haptics would be leading haptics or lagging haptics upon insertion. Then, once inside the capsular bag one of the two leading (or lagging) haptics would have to be rotated about 180° until it is properly positioned to the opposite side of the optic. It is submitted that such an implantation procedure would be unacceptable as being both complicated and potentially dangerous. In conclusion, Brady et al cannot be understood as suggesting to one of skill in the art that the optic be folded along an axis at right angles to line 3-3 (reference no. 47).

At most, the passage cited by the Examiner at column 8, lines 24-34 of the Brady et al reference, might arguably support an assertion that it would have been obvious to try to achieve Applicant's presently claimed invention. But it is well-settled law that "obvious to try" is an impermissible standard of obviousness under §103. In re O'Farrell, 7 U.S.P.Q. 2d 1673, 1680-81 (Fed. Cir. 1988) ("to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful . . ." is legally erroneous standard under §103).

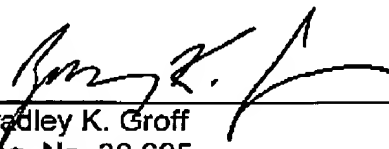
Accordingly, the combination of Uhler and Brady, even if it were not improper, would not teach or suggest every element of Applicant's presently claimed invention or yield a reasonable expectation of success.

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CONCLUSION

In view of the above, it is believed that the application has now been placed in full condition for allowance. Accordingly, early and favorable action is solicited. Should there be any further questions or reservations, the Examiner is urged to telephone Applicants' undersigned attorney at (770) 984-2300.

Respectfully submitted,



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